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CLERK U.S. DISTRICT COURT
CENTRAL DIST. OF CALIF.
LOS ANGELES

UNITED STATES DISTRICT COURT

FOR THE CENTRAL DISTRICT OF CALIFORNIA

19CR00008-RGX

UNITED STATES OF AMERICA,

Plaintiff,

v.

KHK INTERNATIONAL TRADE
ENTERPRISE, INC.,
SHH WORLD TRADING ENTERPRISES,
INC., and
JOHN SEIL LEE,

Defendants.

I N F O R M A T I O N

[18 U.S.C. § 371: Conspiracy;
18 U.S.C. § 545: Importing
Merchandise Contrary to Law; 21
U.S.C. §§ 331(a), 333(a)(2):
Introducing Misbranded Drugs Into
Interstate Commerce; 26 U.S.C.
§ 7206(1): Subscribing to a False
Tax Return; 18 U.S.C.
§§ 981(a)(1)(C), 982, 982(a)(7),
26 U.S.C. § 7206, 28 U.S.C.
§ 2461(c): Criminal Forfeiture; 18
U.S.C. § 2(b): Causing an Act To
Be Done]

The United States Attorney charges:

INTRODUCTORY ALLEGATIONS

At all times relevant to this Information:

A. THE DEFENDANTS AND CO-CONSPIRATOR

1. Defendant JOHN SEIL LEE ("LEE") owned, controlled, and operated four businesses between 2011 and 2017 for the purpose of manufacturing and distributing male sexual enhancement pills that he marketed as herbal remedies but that in fact contained undisclosed Tadalafil, an active pharmaceutical ingredient. From approximately

1 March 2014 to January 2016, defendant LEE owned, controlled, and
2 operated defendant KHK INTERNATIONAL TRADE ENTERPRISE, INC. ("KHK")
3 Beginning in approximately January 2016, defendant LEE owned,
4 controlled, and operated defendant SHH WORLD TRADING ENTERPRISES,
5 INC. ("SHH").

6 2. Defendant KHK was a California corporation registered in
7 March 2014 and located in Diamond Bar, California. Defendant LEE
8 established defendant KHK in order to replace two of his other pill
9 businesses. Defendant KHK marketed and distributed pills that
10 contained undisclosed Tadalafil. Defendant LEE shut down defendant
11 KHK after one of its brands, "X Again" pills, was listed on the
12 website of the United States Food and Drug Administration ("FDA") in
13 December 2015 as a tainted product that contained undisclosed
14 Tadalafil.

15 3. Defendant SHH was a California corporation registered in
16 January 2016 and located in Walnut, California. Defendant LEE
17 established defendant SHH in order to replace defendant KHK. Like
18 defendant KHK, defendant SHH marketed and distributed pills that
19 contained undisclosed Tadalafil. In June 2017, several of defendant
20 SHH's brands, including "X Monster," "Royal Master," and "Own the
21 Knight" were listed the FDA's website as tainted products that
22 contained undisclosed Tadalafil.

23 4. In 2014, defendant LEE hired Co-conspirator #1 as an office
24 assistant to help him operate defendant KHK and then defendant SHH.
25 Co-conspirator #1 worked for defendant LEE until early 2017.

26 B. THE FOOD, DRUG, AND COSMETIC ACT

27 5. The FDA was the federal agency responsible for protecting
28 the health and safety of the American public by enforcing the Food,

1 Drug, and Cosmetic Act ("FDCA"). One of the main purposes of the
2 FDCA was to ensure that human drugs sold were safe, effective, and
3 bore labeling containing only true and accurate information. The
4 FDA's responsibilities under the FDCA included regulating the
5 manufacture, labeling, and distribution of all drugs shipped or
6 received in interstate commerce.

7 6. The FDCA defined a "drug" to include "articles intended for
8 use in the diagnosis, cure, mitigation, treatment, or prevention of
9 disease in man," and "articles (other than food) intended to affect
10 the structure or any function of the body of man." 21 U.S.C.
11 § 321(g)(1)(B) and (C).

12 7. A "prescription drug" was any drug which, "because of its
13 toxicity or other potentiality for harmful effect, or the method of
14 its use, or the collateral measures necessary to its use, [was] not
15 safe for use except under the supervision of a practitioner licensed
16 by law to administer such drug"; or any drug which was "limited by an
17 approved new drug application . . . to use under the professional
18 supervision of a practitioner licensed by law to administer such
19 drug." 21 U.S.C. § 353(b)(1).

20 8. Under the FDCA, "label" was defined as "a display of
21 written, printed, or graphic matter upon the immediate container of
22 any article." 21 U.S.C. § 321(k). The term "labeling," in turn, was
23 defined as "all labels and other written, printed, or graphic matter
24 (1) upon any article or any of its containers or wrappers, or
25 (2) accompanying such article." 21 U.S.C. § 321(m).

26 9. The FDCA prohibited the introduction, delivery for
27 introduction, or causing the introduction or delivery for
28

1 introduction into interstate commerce of any drug that was
2 misbranded. 21 U.S.C. § 331(a).

3 10. Under the FDCA, a drug was deemed to be "misbranded" if,
4 among other things, its labeling was false or misleading in any
5 particular way, 21 U.S.C. § 352(a), or if its labeling failed to bear
6 adequate directions for use, 21 U.S.C. § 352(f)(1). "Adequate
7 directions for use" meant directions under which a layman could use a
8 drug safely and for the purposes for which it was intended. 21
9 C.F.R. § 201.5. By definition, it was not possible to write
10 "adequate directions for use" for a prescription drug.

11 C. TADALAFIL

12 11. Tadalafil was the active pharmaceutical ingredient in the
13 prescription drug Cialis. Cialis was FDA-approved for the treatment
14 of erectile dysfunction.

15 12. Other products containing Tadalafil that were intended to
16 treat a disease in man and/or affect the structure or function of the
17 body of man were "drugs" within the meaning of the FDCA.

18 13. Drugs containing Tadalafil could be particularly harmful to
19 persons taking medications containing nitrates, such as
20 nitroglycerin, because Tadalafil could interact with the nitrates and
21 lower blood pressure to dangerous levels. Men with high blood
22 pressure or heart disease often took nitrates.

23 14. The FDA's approval for Cialis was limited to use under the
24 professional supervision of a practitioner licensed by law to
25 administer such drug; therefore, Cialis was a "prescription drug"
26 under 21 U.S.C. § 353(b)(1)(B). Due to toxicity and other
27 potentially harmful effects (e.g., life-threatening drops in blood
28 pressure, loss of vision, loss of hearing, and prolonged, painful

1 erections that result in permanent injury to the penis), drugs
2 similar to Cialis were not safe for use except under the supervision
3 of a practitioner licensed by law to administer them, and they were
4 thus prescription drugs as well.

5 15. Paragraphs 1-14 are hereby re-alleged and incorporated into
6 each and every count of this Information.

COUNT ONE

[18 U.S.C. § 371]

A. OBJECTS OF THE CONSPIRACY

Beginning on a date unknown to the United States Attorney and continuing to on or about February 22, 2017, in Los Angeles County, within the Central District of California, and elsewhere, defendant LEE, together with others known and unknown to the United States Attorney, including Co-conspirator #1, knowingly conspired and agreed to:

1. Import and bring merchandise (namely, unlabeled bulk Tadalafil), and receive, conceal, buy, sell, and facilitate the transportation, concealment, and sale of such merchandise after importation, knowing the same to have been imported and brought into the United States contrary to law, namely, 21 U.S.C. §§ 331(a) and 352, in violation of Title 18, United States Code, Section 545;

2. Introduce and cause the introduction of misbranded drugs into interstate commerce, with the intent to defraud and mislead, in violation of Title 21, United States Code, Sections 331(a), 352, 333(a)(2); and

3. Defraud the United States or one of its agencies or departments, that is, impede, impair, obstruct, and defeat the lawful and legitimate functions of the FDA in investigating and enforcing federal laws and regulations related to misbranded drugs, in violation of Title 18, United States Code, Section 371.

B. MEANS BY WHICH THE OBJECTS OF THE CONSPIRACY WERE TO BEACCOMPLISHED

The objects of the conspiracy were to be accomplished, in substance, as follows:

1 1. Defendant LEE would order shipments of bulk Tadalafil from
2 suppliers in China.

3 2. To avoid scrutiny from law enforcement, defendant LEE's
4 suppliers would ship the bulk Tadalafil in packages whose labeling
5 (a) falsely described the packages' contents; (b) failed to disclose
6 that the packages contained Tadalafil; and (c) failed to include
7 adequate descriptions for the use of Tadalafil.

8 3. To avoid scrutiny from law enforcement, defendant LEE would
9 have his Chinese suppliers ship the bulk Tadalafil to commercial
10 mailboxes that he controlled in New Jersey and Pennsylvania.

11 4. Defendant LEE would have the commercial mailbox companies
12 that received the Chinese shipments in New Jersey and Pennsylvania
13 repackage the Tadalafil shipments and forward them to mailboxes that
14 defendant LEE controlled in Southern California.

15 5. After defendant LEE received the packages containing the
16 bulk Tadalafil in Southern California, he would cause the bulk
17 Tadalafil to be manufactured into at least 5,500,000 pills that
18 defendant LEE and Co-conspirator #1 would sell to distributors across
19 the United States.

20 6. Defendant LEE would cause the pills sold by defendant LEE
21 and Co-conspirator #1 to be manufactured with levels of Tadalafil
22 significantly higher than the levels in FDA-approved prescription
23 drugs such as Cialis, in order to boost the pills' strength and
24 commercial success, despite his knowledge that Tadalafil could harm
25 the pills' consumers.

26 7. Defendant LEE and Co-conspirator #1 would sell at least \$11
27 million worth of the pills to distributors across the United States
28 in packages with labeling that did not disclose the presence of

1 Tadalafil, and with labeling that falsely stated that no prescription
2 was necessary, even though the pills were in fact prescription drugs.

3 8. When the FDA announced that a certain brand of pills sold
4 by defendant LEE and Co-conspirator #1 was tainted because the pills
5 contained undeclared Tadalafil, defendant LEE and Co-conspirator #1
6 would continue selling their inventories of the same brand despite
7 the FDA's announcement.

8 9. When the FDA announced in December 2015 that co-conspirator
9 KHK's "X Again" pills were tainted because they contained undeclared
10 Tadalafil, defendant LEE would establish a new company, co-
11 conspirator SHH, to sell pills with the same formulas but different
12 brand names, in an attempt to evade federal regulators.

13 10. When the FDA announced that a certain brand of pills sold
14 by co-conspirators KHK or SHH was tainted because the pills contained
15 undeclared Tadalafil, defendant LEE would begin manufacturing pills
16 with identical formulas (including Tadalafil) and coloring, but
17 defendant LEE would change the brand names of the pills in an effort
18 to evade federal regulators. For example:

19 a. After the FDA announced in December 2015 that co-
20 conspirator KHK's white "X Again" pills were tainted because they
21 contained undisclosed Tadalafil, defendant LEE would begin
22 manufacturing a replacement white pill for defendant LEE and Co-
23 conspirator #1 to sell, branded "X Monster," which had the same
24 formula and price as the tainted "X Again" pills and similar labeling
25 that failed to disclose the presence of Tadalafil.

26 b. After the FDA announced in August 2016 that co-
27 conspirator SHH's gold "Master Zone" pills were tainted because they
28 contained undisclosed Tadalafil, defendant LEE would begin

1 manufacturing a replacement gold pill for defendant LEE and Co-
2 conspirator #1 to sell, branded "Royal Master," which had the same
3 formula and price as the tainted "Master Zone" pills and similar
4 labeling that failed to disclose the presence of Tadalafil.

5 c. After the FDA announced in August 2016 that co-
6 conspirator SHH's silver "One More Knight" pills were tainted because
7 they contained undisclosed Tadalafil, defendant LEE would begin
8 manufacturing a replacement silver pill for defendant LEE and Co-
9 conspirator #1 to sell, branded "Own The Knight," which had the same
10 formula and price as the tainted "One More Knight" pills and similar
11 labeling that failed to disclose the presence of Tadalafil.

12 11. Defendant LEE and Co-conspirator #1 would market, sell, and
13 distribute the newly branded pills by informing their distributors
14 that the newly branded pills had formulas that were identical to the
15 pills that they were replacing due to the FDA's notices.

16 C. OVERT ACTS

17 On or about the following dates, in furtherance of the
18 conspiracy and to accomplish its objects, defendant LEE, and others
19 both known and unknown to the United States Attorney, including Co-
20 conspirator #1, committed various overt acts within the Central
21 District of California and elsewhere, including, but not limited to,
22 the following:

23 Overt Act No. 1: On or about March 5, 2014, defendant LEE
24 caused co-conspirator KHK to be established as a corporation to
25 replace defendant LEE's previous companies as the entity through
26 which defendant LEE would manufacture and sell misbranded drugs
27 containing undeclared Tadalafil.

1 Overt Act No. 2: On or about December 18, 2015, when the FDA
2 issued a public notice on its website announcing that co-conspirator
3 KHK's white "X Again" pills were tainted because they contained
4 undisclosed Tadalafil, defendant LEE continued selling the white "X
5 Again" pills despite the FDA's notice.

6 Overt Act No. 3: On or about December 21, 2015, Co-
7 conspirator #1 shipped approximately 6,000 white "X Again" pills to
8 defendant LEE's distributor in Northridge, California.

9 Overt Act No. 4: On or about December 22, 2015, Co-
10 conspirator #1 shipped approximately 5,300 white "X Again" pills to
11 defendant LEE's distributor in Santa Clarita, California.

12 Overt Act No. 5: On or about December 22, 2015, Co-
13 conspirator #1 shipped approximately 3,312 white "X Again" pills to
14 defendant LEE's distributor in Tampa, Florida.

15 Overt Act No. 6: On or about December 29, 2015, Co-
16 conspirator #1 shipped approximately 2,040 white "X Again" pills to
17 defendant LEE's distributor Salem, Oregon.

18 Overt Act No. 7: In or about January 2016, defendant LEE
19 caused co-conspirator SHH to be established as a corporation to
20 replace co-conspirator KHK as the entity through which defendant LEE
21 would manufacture and sell misbranded drugs containing undeclared
22 Tadalafil.

23 Overt Act No. 8: In or about February 2016, following the
24 FDA's public notice that co-conspirator KHK's white "X Again" pills
25 were tainted because they contained undisclosed Tadalafil, defendant
26 LEE and Co-Conspirator #1 began marketing a replacement white pill,
27 branded "X Monster," which had the same formula and price as the
28

1 tainted "X Again" pills and similar labeling that failed to disclose
2 the presence of Tadalafil.

3 Overt Act No. 9: On or about February 25, 2016, Co-
4 conspirator #1 informed one of defendant LEE's distributors in
5 Paramount, California that "[u]nfortunately we are out of the XA [X
6 Again] products. We will be replacing it with X-Monster (same
7 product but different name) and will be ready to ship next
8 Wednesday."

9 Overt Act No. 10: On or about March 1, 2016, Co-conspirator #1
10 informed defendant LEE's distributor in Southern Pines, North
11 Carolina that the new "X Monster" white pills were now in stock and
12 that "[t]he formula hasn't changed" from its predecessor, the white
13 "X Again" pills.

14 Overt Act No. 11: On or about March 1, 2016, Co-conspirator #1
15 shipped approximately 12,918 white "X Monster" pills to defendant
16 LEE's distributor in Southern Pines, North Carolina.

17 Overt Act No. 12: On or about March 1, 2016, Co-conspirator #1
18 shipped approximately 2,880 white "X Monster" pills to one of
19 defendant LEE's distributors in Paramount, California.

20 Overt Act No. 13: On or about March 2, 2016, Co-conspirator #1
21 informed defendant LEE's distributor in Salem, Oregon that "[n]ot
22 sure if you were aware but X-Again was pulled by the FDA. So now, we
23 are replacing XA with a new brand called X-monster that has the same
24 formula but slight changes on package artwork."

25 Overt Act No. 14: On or about March 2, 2016, Co-conspirator #1
26 shipped approximately 1,200 white "X Monster" pills to defendant
27 LEE's distributor in Salem, Oregon.

1 Overt Act No. 15: On or about March 14, 2016, Co-conspirator
2 #1 informed defendant LEE's distributor in Broomfield, Colorado that
3 "[o]ur new item is called X-Monster and it has the same specs and
4 pricing as the X-Again."

5 Overt Act No. 16: On or about March 25, 2016, Co-conspirator
6 #1 shipped approximately 1,200 white "X Monster" pills to defendant
7 LEE's distributor in Broomfield, Colorado.

8 Overt Act No. 17: On or about August 16, 2016, when the FDA
9 issued a public notice on its website announcing that co-conspirator
10 SHH's gold "Master Zone" pills were tainted because they contained
11 undisclosed Tadalafil, defendant LEE continued selling the gold
12 "Master Zone" pills despite the FDA's notice.

13 Overt Act No. 18: On or about August 16, 2016, when the FDA
14 issued a public notice on its website announcing that co-conspirator
15 SHH's silver "One More Knight" pills were tainted because they
16 contained undisclosed Tadalafil, defendant LEE continued selling the
17 silver "One More Knight" pills despite the FDA's notice.

18 Overt Act No. 19: On or about August 16, 2016, Co-conspirator
19 #1 shipped approximately 11,040 gold "Master Zone" pills to defendant
20 LEE's distributor in Santa Clarita, California.

21 Overt Act No. 20: On or about August 16, 2016, Co-conspirator
22 #1 shipped approximately 15,360 silver "One More Knight" pills to
23 defendant LEE's distributor in Santa Clarita, California.

24 Overt Act No. 21: On or about August 16, 2016, Co-conspirator
25 #1 shipped approximately 1,471 gold "Master Zone" pills to defendant
26 LEE's distributor in Northridge, California.

1 Overt Act No. 22: On or about August 16, 2016, Co-conspirator
2 #1 shipped approximately 5,160 silver "One More Knight" pills to
3 defendant LEE's distributor in Northridge, California.

4 Overt Act No. 23: On or about August 18, 2016, Co-conspirator
5 #1 shipped approximately 6,120 silver "One More Knight" pills to
6 defendant LEE's distributor in Southern Pines, North Carolina.

7 Overt Act No. 24: On or about August 26, 2016, Co-conspirator
8 #1 shipped approximately 1,800 gold "Master Zone" pills to defendant
9 LEE's distributor in Catonsville, Maryland.

10 Overt Act No. 25: On or about August 26, 2016, Co-conspirator
11 #1 shipped approximately 1,200 silver "One More Knight" pills to
12 defendant LEE's distributor in Catonsville, Maryland.

13 Overt Act No. 26: On or about August 26, 2016, Co-conspirator
14 #1 shipped approximately 5,400 gold "Master Zone" pills to defendant
15 LEE's distributor in Santa Clarita, California.

16 Overt Act No. 27: On or about August 26, 2016, Co-conspirator
17 #1 shipped approximately 5,360 silver "One More Knight" pills to
18 defendant LEE's distributor in Santa Clarita, California.

19 Overt Act No. 28: On or about August 26, 2016, Co-conspirator
20 #1 shipped approximately 3,000 silver "One More Knight" pills to one
21 of defendant LEE's distributors in Paramount, California.

22 Overt Act No. 29: On or about August 26, 2016, Co-conspirator
23 #1 shipped approximately 4,800 silver "One More Knight" pills to
24 defendant LEE's distributor in Claymont, Delaware.

25 Overt Act No. 30: On or about August 29, 2016, Co-conspirator
26 #1 shipped approximately 1,800 silver "One More Knight" pills to
27 defendant LEE's distributor in Southern Pines, North Carolina.

1 Overt Act No. 31: On or about August 29, 2016, Co-conspirator
2 #1 informed defendant LEE's distributor in Toronto, Canada that "OMK
3 [One More Knight] and MZ [Master Zone] were recalled by the FDA and
4 we are currently out of stock. But if you want the products, we can
5 ship it out by Friday."

6 Overt Act No. 32: On or about August 29, 2016, Co-conspirator
7 #1 informed defendant LEE's distributor in Toronto, Canada that "We
8 are working to change the name of both OMK [One More Knight] and MZ
9 [Master Zone] like we did with XMonster but it will take a few weeks.
10 Same price and formula just different name and small changes on
11 packaging."

12 Overt Act No. 33: On or about September 6, 2016, Co-
13 conspirator #1 shipped approximately 9,600 gold "Master Zone" pills
14 to defendant LEE's distributor in Toronto, Canada.

15 Overt Act No. 34: On or about September 28, 2016, Co-
16 conspirator #1 informed defendant LEE's distributor in Augusta,
17 Georgia that "unfortunately OMK [One More Knight] was put on the FDA
18 list but we have a replacement product coming out soon. The new
19 product will have same formula and similar package but using [a]
20 different name and should be ready to ship around the second week of
21 October."

22 Overt Act No. 35: In or about early October 2016, following
23 the FDA's public notice that co-conspirator SHH's gold "Master Zone"
24 pills were tainted because they contained undisclosed Tadalafil,
25 defendant LEE and Co-conspirator #1 began marketing a replacement
26 gold pill, branded "Royal Master," which had the same formula and
27 price as the tainted "Master Zone" pills and similar labeling that
28 failed to disclose the presence of Tadalafil.

1 Overt Act No. 36: In or about early October 2016, following
2 the FDA's public notice that co-conspirator SHH's silver "One More
3 Knight" pills were tainted because they contained undisclosed
4 Tadalafil, defendant LEE and Co-conspirator #1 began marketing a
5 replacement silver pill, branded "Own The Knight," which had the same
6 formula and price as the tainted "One More Knight" pills and similar
7 labeling that failed to disclose the presence of Tadalafil.

8 Overt Act No. 37: On or about October 5, 2016, Co-conspirator
9 #1 informed defendant LEE's distributor in Baltimore, Maryland that
10 "All prices and specs are the same" for the new gold "Royal Master"
11 pill (as compared to its predecessor, the gold "Master Zone" pill)
12 and for the new silver "Own The Knight" pill (as compared to its
13 predecessor, the silver "One More Knight" pill).

14 Overt Act No. 38: On or about October 14, 2016, Co-conspirator
15 #1 shipped approximately 600 gold "Royal Master" pills to one of
16 defendant LEE's distributors in Paramount, California.

17 Overt Act No. 39: On or about October 14, 2016, Co-conspirator
18 #1 shipped approximately 600 silver "Own The Knight" pills to one of
19 defendant LEE's distributors in Paramount, California.

20 Overt Acts Nos. 40 through 45: On or about the following dates,
21 defendant LEE, and others, caused the following shipments containing
22 unlabeled bulk Tadalafil to be imported from China into the United
23 States:

24 //

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OVERT ACT	DATE	PARCEL WEIGHT	DESTINATION
40	10/22/2016	5.094 kg	Windsor, New Jersey
41	10/27/2016	5.176 kg	East Windsor, New Jersey
42	11/1/2016	10.9 kg	East Windsor, New Jersey
43	12/3/2016	5.118 kg	Hillsborough, New Jersey
44	12/9/2016	5.12 kg	East Windsor, New Jersey
45	1/27/2017	5.65 kg	Hillsborough, New Jersey

Overt Acts Nos. 46 through 58: On or about the following dates, defendant LEE, and others, caused the following shipments containing unlabeled bulk Tadalafil to be delivered to defendant LEE in the Central District of California from commercial mailbox companies on the East Coast that, on defendant LEE's behalf, had received and repackaged the same shipments from China:

OVERT ACT	DATE	TRACKING NUMBER
46	11/22/2016	784695188477
47	12/30/2016	785170993499
48	1/5/2017	809523700312
49	1/5/2017	809523700312
50	1/6/2017	785230093828
51	1/20/2017	785355591159
52	1/26/2017	785398051636
53	1/26/2017	785398051636
54	2/2/2017	718084775869
55	2/2/2017	718084775869
56	2/10/2017	785506983365
57	2/9/2017	718084776637
58	2/9/2017	718084776637

1 Overt Act No. 59: On or about October 26, 2016, Co-conspirator
2 #1 shipped approximately 600 gold "Royal Master" pills to defendant
3 LEE's distributor in Baltimore, Maryland.

4 Overt Act No. 60: On or about October 26, 2016, Co-conspirator
5 #1 informed defendant LEE's distributor in Salem, Oregon, in response
6 to being asked, "Is Royal master replacing Master Zone? Is one More
7 Knight being replaced?," that "Yes, both items were put on the FDA
8 list back in August. . . . Sorry if we forgot to let you know!
9 Master Zone is being replaced by Royal Master and One More Knight is
10 being replaced by Own The Knight, but nothing changes on the
11 formula."

12 Overt Act No. 61: On or about October 27, 2016, Co-conspirator
13 #1 informed defendant LEE's distributor in Augusta Georgia, in
14 response to being asked, "do u have another pill for one more
15 knight," that "Yes, we replaced it with Own The Knight, same
16 formula."

17 Overt Act No. 62: On or about October 28, 2016, Co-conspirator
18 #1 shipped approximately 600 silver "Own The Knight" pills to
19 defendant LEE's distributor in Baltimore, Maryland.

20 Overt Act No. 63: On or about October 28, 2016, Co-conspirator
21 #1 shipped approximately 1,200 silver "Own The Knight" pills to
22 defendant LEE's distributor in Salem, Oregon.

23 Overt Act No. 64: On or about November 1, 2016, Co-conspirator
24 #1 shipped approximately 600 silver "Own The Knight" pills to
25 defendant LEE's distributor in Augusta, Georgia.

26 Overt Act No. 65: On or about January 27, 2017, Co-conspirator
27 #1 shipped approximately 3,000 white "X Monster" pills to defendant
28 LEE's distributor in Tampa, Florida.

1 Overt Act No. 66: On or about January 27, 2017, Co-conspirator
2 #1 shipped approximately 600 silver "Own The Knight" pills to
3 defendant LEE's distributor in Tampa, Florida.

COUNT TWO

[18 U.S.C. §§ 545, 2(b)]

On or about February 9, 2017, in Los Angeles County, within the Central District of California, defendant LEE fraudulently and knowingly imported and brought, and willfully caused to be imported and brought, merchandise, namely, two parcels of unlabeled bulk Tadalafil, into the United States contrary to law, that is, with labeling that was false and misleading as to the parcels' contents, labels that did not contain accurate statements of the packages' contents in terms of weight, measure, and numerical count, and labeling that did not bear adequate directions for use, contrary to the FDCA, Title 21, United States Code, Sections 331(a) and 352(a)(1), (b), (f).

COUNTS THREE AND FOUR

[21 U.S.C. §§ 331(a), 352, 333(a)(2)]

On or about the following dates, in Los Angeles County, within the Central District of California, defendants KHK and LEE introduced and willfully caused the introduction of the following misbranded drugs into interstate commerce, with the intent to defraud and mislead the Food and Drug Administration. The drugs were misbranded because their labeling was false and misleading, in violation of the FDCA, in one or more of the following ways: (1) the drugs' labeling falsely and misleadingly stated "no prescription necessary," even though they were prescription drugs that contained high doses of Tadalafil; and (2) none of the labeling disclosed the presence of the active pharmaceutical ingredient Tadalafil in the drugs.

COUNT	DATE	PRODUCT	QUANTITY	RECIPIENT'S LOCATION
THREE	12/22/2015	X Again	3,312	Tampa, Florida
FOUR	12/29/2015	X Again	2,040	Salem, Oregon

COUNTS FIVE AND SIX

[21 U.S.C. §§ 331(a), 352, 333(a)(2)]

On or about the following dates, in Los Angeles County, within the Central District of California, defendants SHH and LEE introduced and willfully caused the introduction of the following misbranded drugs into interstate commerce, with the intent to defraud and mislead the Food and Drug Administration. The drugs were misbranded because their labeling was false and misleading, in violation of the FDCA, in one or more of the following ways: (1) the drugs' labeling falsely and misleadingly stated "no prescription necessary," even though they were prescription drugs that contained high doses of Tadalafil; and (2) none of the labeling disclosed the presence of the active pharmaceutical ingredient Tadalafil in the drugs.

COUNT	DATE	PRODUCT	QUANTITY	RECIPIENT'S LOCATION
FIVE	8/26/2016	One More Knight	4,800	Claymont, Delaware
SIX	8/29/2016	One More Knight	1,800	Southern Pines, North Carolina

COUNT SEVEN

[26 U.S.C. § 7206(1); 18 U.S.C. § 2(b)]

On or about October 15, 2017, in Los Angeles County, within the Central District of California, defendant LEE willfully made and subscribed, and willfully caused to be made and subscribed, to a materially false U.S. Individual Income Tax Return (Form 1040), for the calendar year 2016, which was filed with the Internal Revenue Service and verified in a written declaration that it was made under penalty of perjury, and which income tax return defendant LEE did not believe to be true as to every material matter, in that defendant LEE willfully omitted from that return income of approximately \$1,148,716.

FORFEITURE ALLEGATION ONE

[18 U.S.C. §§ 982, 545; 28 U.S.C. § 2461(c)]

1. Pursuant to Rule 32.2(a) of the Federal Rules of Criminal Procedure, notice is hereby given that the United States of America will seek forfeiture as part of any sentence, pursuant to Title 18, United States Code, Sections 982 and 545, and Title 28, United States Code, Section 2461(c), in the event of any defendant's conviction of the offenses set forth in either or both of Counts One and/or Two of this Information.

2. Any defendant so convicted shall forfeit to the United States the following:

(a) All right, title, and interest in any and all property, real or personal constituting, or derived from, any proceeds obtained, directly or indirectly, as a result of each such offense;

(b) Any and all merchandise introduced into the United States in violation of Title 18, United States Code, Section 545, or the value thereof; and

(c) To the extent such property is not available for forfeiture, a sum of money equal to the total value of the property described in subparagraphs (a) and (b).

3. Pursuant to Title 21, United States Code, Section 853(p), as incorporated by Title 18, United States Code, Section 982(b) and Title 28, United States Code, Section 2461(c), any defendant so convicted shall forfeit substitute property, up to the total value of the property described in the preceding paragraph if, as the result of any act or omission of said defendant, the property described in the preceding paragraph, or any portion thereof: (a) cannot be located upon the exercise of due diligence; (b) has been transferred,

1 sold to or deposited with a third party; (c) has been placed beyond
2 the jurisdiction of the Court; (d) has been substantially diminished
3 in value; or (e) has been commingled with other property that cannot
4 be divided without difficulty.

FORFEITURE ALLEGATION TWO

[18 U.S.C. § 982(a)(7); 28 U.S.C. § 2461(c)]

1. Pursuant to Rule 32.2(a), Fed. R. Crim. P., notice is hereby given that the United States will seek forfeiture as part of any sentence, pursuant to Title 18, United States Code, Section 982(a)(7) and Title 28, United States Code, Section 2461(c), in the event of any defendant's conviction of the offenses set forth in any of Counts Three through Six of this Information.

2. Any defendant so convicted shall forfeit to the United States of America the following:

(a) All right, title, and interest in any and all property, real or personal, that constitutes or is derived, directly or indirectly, from the gross proceeds traceable to the commission of any offense of conviction; and

(b) To the extent such property is not available for forfeiture, a sum of money equal to the total value of the property described in subparagraph (a).

3. Pursuant to Title 21, United States Code, Section 853(p), as incorporated by Title 28, United States Code, Section 2461(c), and Title 18, United States Code, Section 982(b), the convicted defendant shall forfeit substitute property, up to the total value of the property described in the preceding paragraph if, as a result of any act or omission of said defendant, the property described in the preceding paragraph, or any portion thereof (a) cannot be located upon the exercise of due diligence; (b) has been transferred, sold to or deposited with a third party; (c) has been placed beyond the jurisdiction of the Court; (d) has been substantially diminished in

1 value; or (e) has been commingled with other property that cannot be
2 divided without difficulty.

FORFEITURE ALLEGATION THREE

[26 U.S.C. § 7206; 28 U.S.C. § 2461(c)]

1. Pursuant to Rule 32.2(a) of the Federal Rules of Criminal Procedure, notice is hereby given that the United States of America will seek forfeiture as part of any sentence, pursuant to Title 26, United States Code, Section 7206, and Title 28, United States Code, Section 2461(c), in the event of any defendant's conviction of the offense set forth in Count Seven of this Information.

2. Any defendant so convicted shall forfeit to the United States of America the following:

(a) Any property sold or removed by the defendant in fraud of the internal revenue laws, or with design to avoid payment of such tax, or which was removed, deposited, or concealed, with intent to defraud the United States of such tax or any part thereof;

(b) All property manufactured into property of a kind subject to tax for the purpose of selling such taxable property in fraud of the internal revenue laws, or with design to evade the payment of such tax;

(c) All property whatsoever, in the place or building, or any yard or enclosure, where the property described in subsection (a) or (b) is found, or which is intended to be used in the making of property described in subsection (a), with intent to defraud the United States of tax or any part thereof, on the property described in subsection (a);

(d) All property used as a container for, or which shall have contained, property described in subsection (a) or (b);

(e) Any property (including aircraft, vehicles, vessels, or draft animals) used to transport or for the deposit or concealment

1 of property described in subsection (a) or (b), or any property used
2 to transport or for the deposit or concealment of property which is
3 intended to be used in the making or packaging of property described
4 in subsection (a); and

5 (f) To the extent that such property is not available for
6 forfeiture, a sum of money equal to the total value of the property
7 described in this paragraph.

8 3. Pursuant to Title 21, United States Code, Section 853(p),
9 as incorporated by Title 18, United States Code, Section 982(b) and
10 Title 28, United States Code, Section 2461(c), the defendant, if so
11 convicted, shall forfeit substitute property, up to the total value
12 of the property described in the preceding paragraph if, as the
13 result of any act or omission of the defendant, the property
14 described in the preceding paragraph, or any portion thereof (a)
15 cannot be located upon the exercise of due diligence; (b) has been

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1 transferred, sold to or deposited with a third party; (c) has been
2 placed beyond the jurisdiction of the court; (d) has been
3 substantially diminished in value; or (e) has been commingled with
4 other property that cannot be divided without difficulty.

5
6 NICOLA T. HANNA
United States Attorney

7 

8 *Scott Garinger*
Deputy Chief, Criminal Division For:

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